AZOI

Kito

User Manual

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About Azoi

We, at Azoi, have been working on “monitoring technology” which would enable people to track their health. We intend to provide consumers an easy and accessible way to measure their critical vitals in a home environment. Azoi’s team includes experts in sensor technology, product design, application development and quality assurance to ensure that the delivered product conforms to the prescribed requirements.

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For any assistance, write to Azoi at help@azoi.com.

1 About Kito

Welcome and thanks for your purchase!

We are glad that you are a part of the Kito family now.

Kito is a hand-held medical device that measures body vitals in adults. It measures human skin temperature, oxygen saturation of arterial hemoglobin (SpO2), respiration rate, heart rate and electrocardiographic activity (ECG).

Kito uses a 1 Lead ECG mechanism to capture ECG; an NTC thermistor based sensor to measure skin temperature; and reflective SpO2 technology to measure blood oxygen saturation. Heart rate is calculated using the ECG values. Respiration rate is derived from the ECG and Photoplethysmography (PPG) values. Kito connects to the Kito mobile app through Bluetooth Low Energy (BLE) technology. The recorded measurements are displayed in the Kito mobile app and stored on a secure Azync Cloud Platform. For indoor use only and non-water resistance.

2 Important Information

2.1 Safety

If you are a patient with a chronic illness or other medical conditions, please consult your doctor before using Kito. Please note that use of Kito is not a replacement for regular check-ups with your doctor. The user manual will guide you to operate Kito and understand your readings.

2.2 Intended Use

Kito is a portable, handheld, non-invasive device for measuring body vitals. It is intended to measure skin temperature, oxygen saturation of arterial hemoglobin (SpO2), respiration rate, heart rate and electrocardiographic activity. The device is intended to be used by adults in a dry, clean and stable environment to track their own vitals and make informed lifestyle decisions pertaining to their health. The device allows the user to check present measurements, view previous measurements and share the data with person(s) of their choice.

2.3 Contraindication

Kito does not detect or diagnose medical conditions. The readings displayed or stored by Kito should not be used for any specific clinical diagnosis, self-medication, medical checkup substitution, and making critical medical decisions.

Kito should not be used while charging, with cold or wet hands, in a dusty environment, or while moving. Kito is not waterproof.

3 Unpacking

3.1 Package Contents

The package contains the Kito device and a Quick Start Guide along with the charger and a USB 2.0 cable as accessories.

3.1.1 Device Unpacking

- Open the box from the slide flap.
- Take out the transparent plastic cover.
- Take out Kito and put aside the white tray.
- Remove the Quick Start Guide to access the charger tray.
- Take out the charging cable.
- Remove the desiccant package and the charger.

3.2 System Requirements for App installation

Kito application's system prerequisites are:

iOS

- iOS 7 or higher
- Apple ID to access the App store

Android

- Android 4.3 or higher
- Play store ID

Additionally, your mobile device must natively support Bluetooth Low Energy and have internet connectivity.

3.3 Know your Device

Kito Device

Details:

- **01 and 02 – ECG Electrode 1 and Electrode 2**
- **03 – Skin Temperature Sensor**
- **04 – Blood Oxygen Saturation Sensor**
- **05 –Switch**
- **06 – Polycarbonate Body**

Kito Charger

3.4 Charge your Device

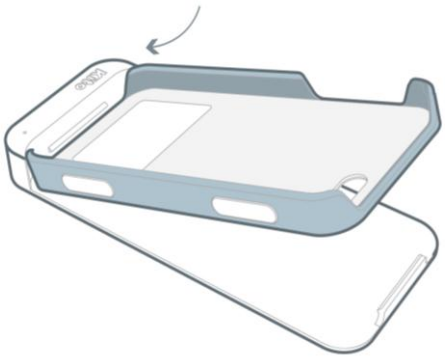


Figure 1: Put Kito vertically on the base of the charger ensuring that the charging contacts at the bottom meet.

Figure 2: Press gently at the top to firmly secure the device.

Connect the USB cable and turn ON the power supply. If you see a Blue light on the charger, Kito is charging.

Indications

The Switch (05) has a light which indicates the Kito battery level. Please refer to the following table to understand the indications:

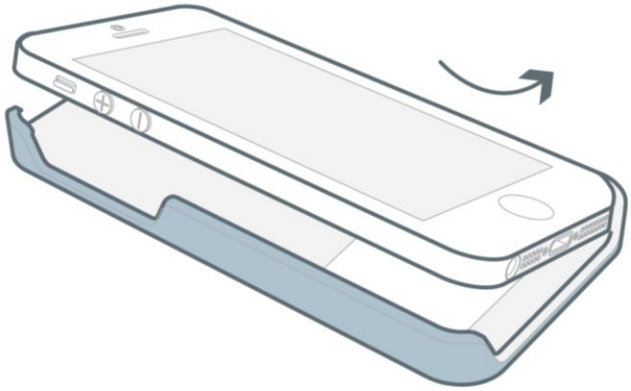
Kito Light	Continuous Light	• Kito is active and the battery is sufficiently charged.
	Blinking Light	• Kito is active, but the battery is too low to measure the vitals.
Charger Light	Blue Light	• Charger is connected to the power source and is charging Kito.
	White Light	• Kito is fully charged.

4 Get Started

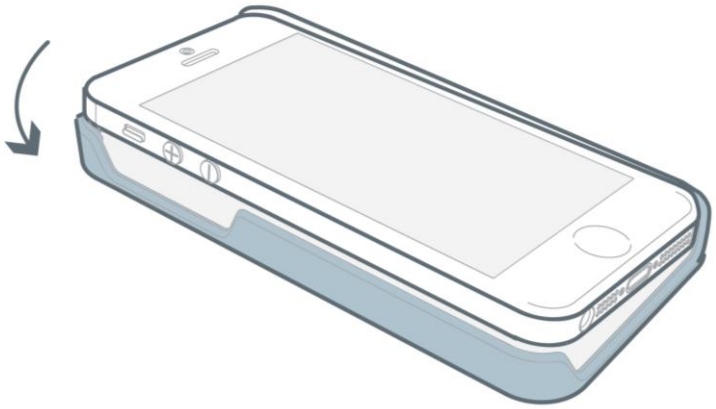
4.1 Setup

Note: *For Android users, Kito will work as a stand-alone unit. Please keep Kito in close proximity to your mobile device.*

Secure Kito onto the back of your mobile device as shown in the illustration. Begin with inserting the right side of your phone towards the side with the electrodes.



Gently push your phone into the Kito cradle. Make sure your phone and Kito are firmly clasped together.



Note: *Please charge the device completely before using it.*

4.2 Install the App

Download and install “Kito” app from the App Store or GooglePlay store. After successful installation, the Kito icon ( ) will show up on you screen. Tap the icon to launch the Kito app.

4.3 Create an Account

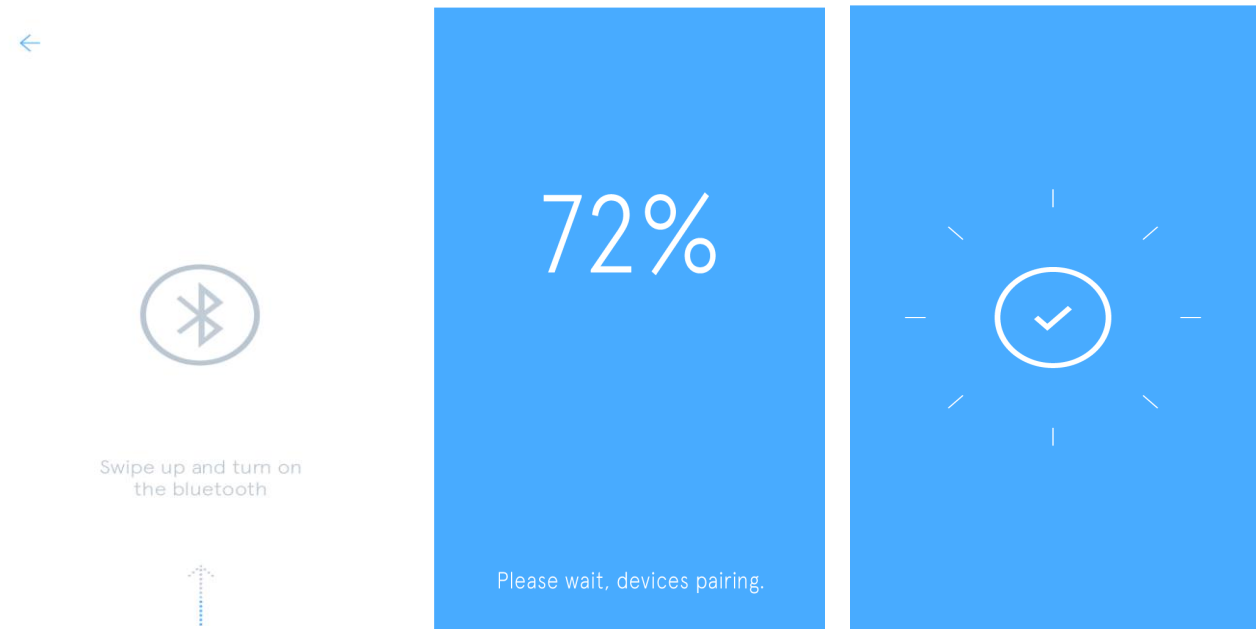
For the first time usage, you need to Sign-Up for creating your Kito account. To try Kito on the go, tap “Try It!” But before going any further, you will need to pair Kito with the app. Please see the pairing process (Pair your Device).

After you have successfully paired Kito, follow the on-screen instructions to create your Kito account. Information such as Gender, Age, Weight and Height helps Kito determine the ideal range of body vitals for you. To add a new user, tap and Sign-Up to create another Kito account.

4.4 Pair your Device

Kito communicates with the Kito app via Bluetooth Low Energy technology. To use Kito, you need to pair it with the Kito app. Turn ON the Switch and follow on-screen instructions.

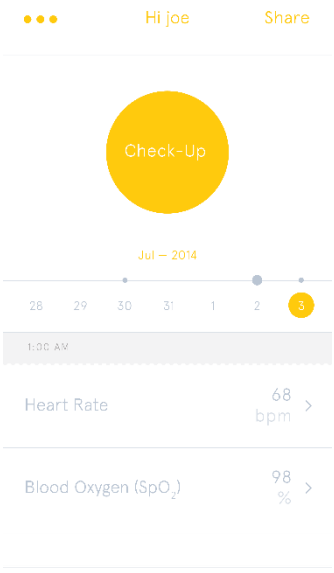
Note: *Please turn Bluetooth ON from the "Settings" menu on your mobile device for pairing.*



You need to pair Kito with the Kito app only for the very first time. For subsequent usage, pairing is not required unless you use Kito with a different mobile device or change Kito.

4.5 Do a Test Reading

Press the Switch to turn ON Kito. Next, tap "Check-Up" and hold Kito with both hands as shown in the illustration to start taking a reading.



The White LED on the Power Switch glows for 30 seconds after you turn it ON. You can take a reading within these 30 seconds. If that period has lapsed, you need to turn the switch ON again to record a reading.

When taking a reading:

- Hold Kito gently; do not apply pressure on the indicated points.
- Keep your shoulder and arms relaxed.
- Do not take readings while you are in a state of motion.
- Do not take readings while your mobile device is being charged or immediately after charging it. Charging generates heat and this may affect your readings.

In case of any temporary interruption like a call, the Kito app goes in the background mode and resumes app dashboard when the interruption ends.

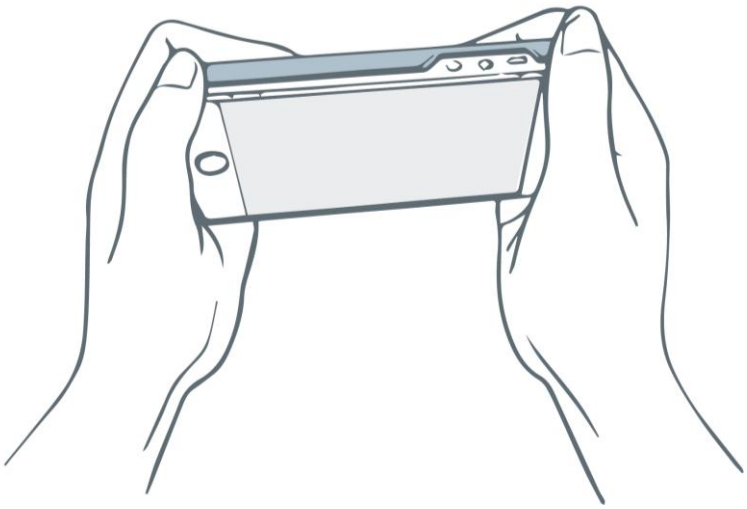
After the recording duration ends, you can see your Reading Card which shows the measured values corresponding to each body vital. Tap an individual vital to see its graphical representation.

To save the readings to your account, tap “Save” at the top-right corner of the dashboard. You can review the saved readings later from your timeline. Please see the section Your Health Data for more details.

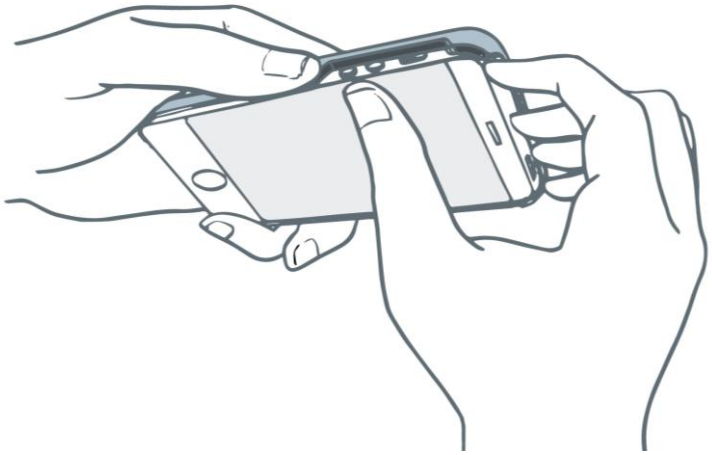
You can choose to discard the current reading and take a reading again.

4.6 Remove Kito

To remove Kito, use your thumbs to apply pressure on the corners of the Kito device and push it outwards.



Use your fingers to pull out the phone from the space created at the top corner.



5 Your Health Data

5.1 Know your Vitals

Before proceeding further, let us quickly understand what the vitals measured by Kito mean:

Heart Rate - Heart Rate is the number of times your heart beats in a minute and is an important indicator of cardiovascular fitness. The Heart Rate of a healthy adult in a relaxed state, lies in the range of 60 to 100 beats per minute.

Skin Temperature - Skin Temperature majorly depends on the surrounding air temperature and time spent in an environment. External factors such as chilly winds and humidity can cause changes in the skin temperature.

Electrocardiogram (ECG) - ECG, alternatively known as EKG, is a test that records the heart's electrical activity. In simple terms, the heart's activity is captured and plotted on a waveform graph.

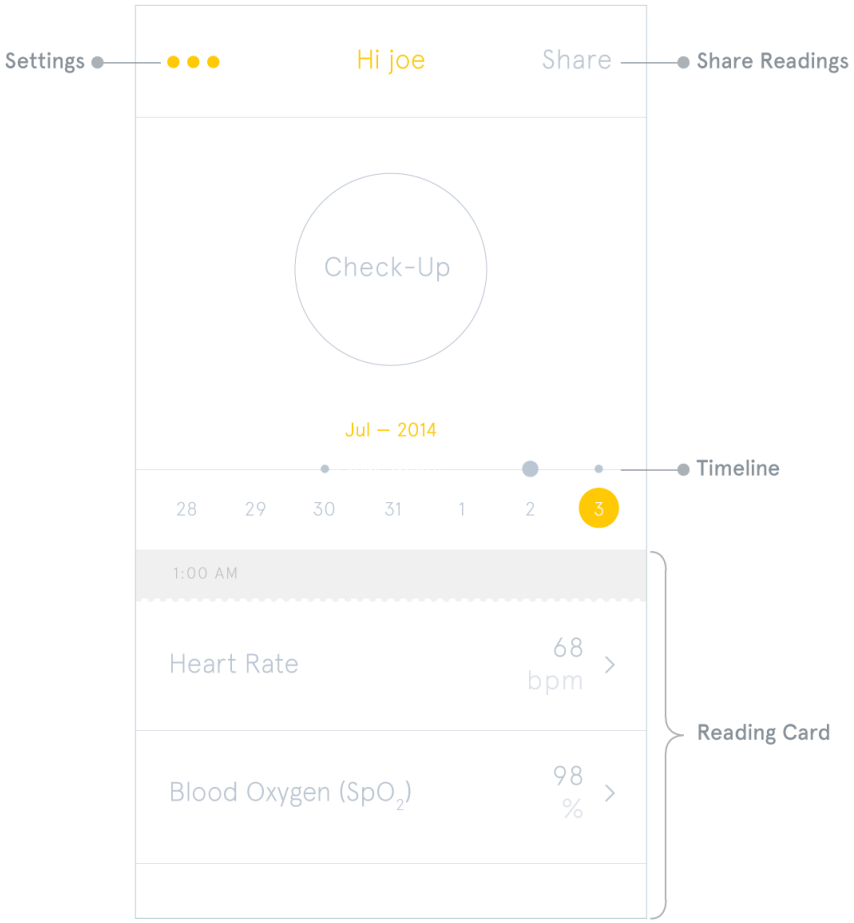
Blood Oxygen Saturation (SpO2) - SpO2 is a percentage of Oxygen Saturation in the blood. For an adult, the blood oxygen level should ideally range from 95 to 100 percent in a relaxed state.

Respiration - The Respiration Rate is the number of breaths taken per minute. Normal Respiration Rate for an adult in a relaxed state, ranges from 12 to 18 breaths per minute. Take a deep breath and read on.

Note: *A more detailed explanation regarding the vitals can be found in the Kito mobile app. Go to Settings (● ● ●) and tap "About Vitals" for additional information.*

5.2 The Dashboard

Dashboard is your personalized space to take a new reading, look up the existing readings, and modify default settings.



Timeline: The Dashboard timeline displays dates of the current month sequentially along a line. You can slide the timeline to move back and forth and review older readings. The dots adjacent to the dates expand and shrink based on the number of readings taken during a day- a larger dot denotes multiple reading records.

Reading Card: One reading card holds the details of a single reading. Reading cards corresponding to the date selected in the timeline, will be visible at the bottom of your screen. If you have taken

multiple readings on a single day, the latest reading will be visible and the rest of the reading cards will remain collapsed under the Reading Card area.

Share Readings: To share readings, tap “Share” and select the Reading Cards you would like to send via email. You can share up to 20 readings via email.

Settings: Tap Settings (🟡 🟡 🟡) to set a reminder, edit your Profile, sync Fitbit™, apply a security lock, register email addresses to share reports, apply ECG Filter, alter the measurement unit for the temperature vital and upgrade Firmware.

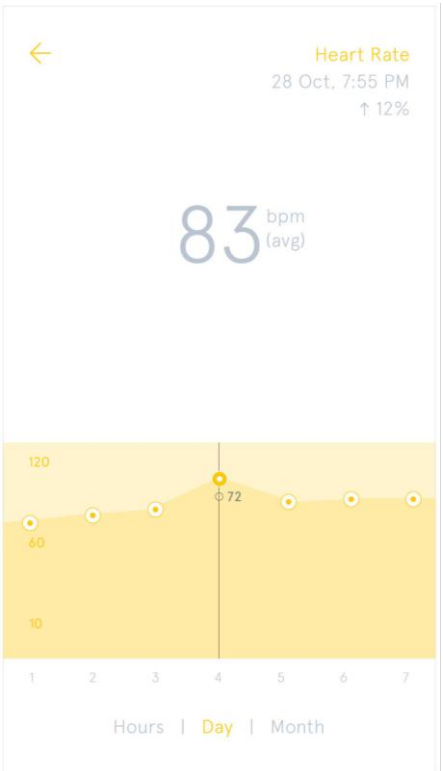
Note: *Kito and the mobile device must be sufficiently charged before upgrading the firmware. Once you initiate the firmware upgrade, you will not be able to access the application until the firmware installation is complete.*

5.3 Readings by Type

The graphical representation of readings helps you compare your readings taken over a course of time. Tap a vital of your preference to see its corresponding graph after you have taken a reading. To review an older reading, go to the Dashboard and select the date for which you want to look up the readings. Tap individual reading cards to expand and view the details.

5.3.1 Heart Rate

Tap Heart Rate to plot heart rate value on the chart. Here, the X-axis (horizontal) corresponds to the hours/day/month units, and the Y-axis (vertical) corresponds to the measuring unit for Heart Rate which is BPM.



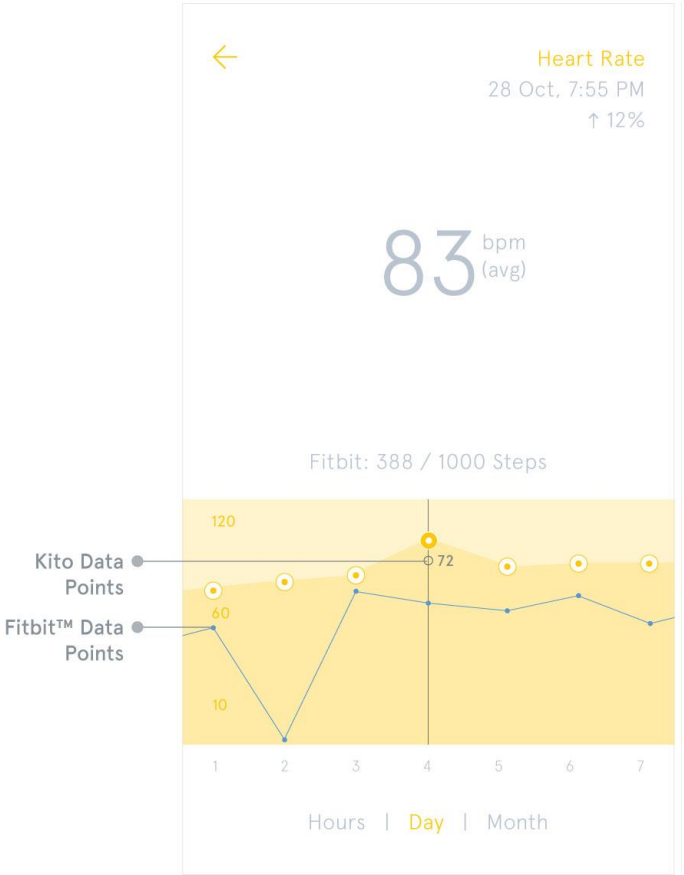
The values on Y-axis show the range for Heart Rate.

Note: *The range shown in the application is only a reference and may not apply to everyone. Consult your doctor to know the appropriate range for you.*

The point plotted on the graph denotes a single reading. The reading which you are reviewing will be displayed at the center of the screen.

The value in percentage at the top-right of your screen represents the percentage difference between your latest reading and the one being reviewed.

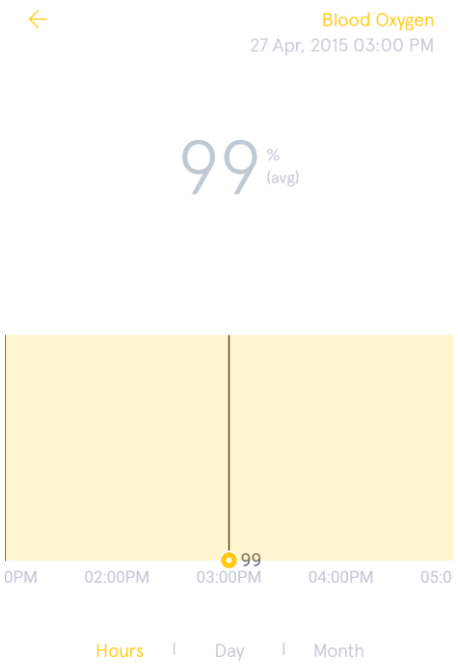
The app overlays the information received from Fitbit™ over its own reading of vitals to indicate how your daily activity is affecting your vitals.



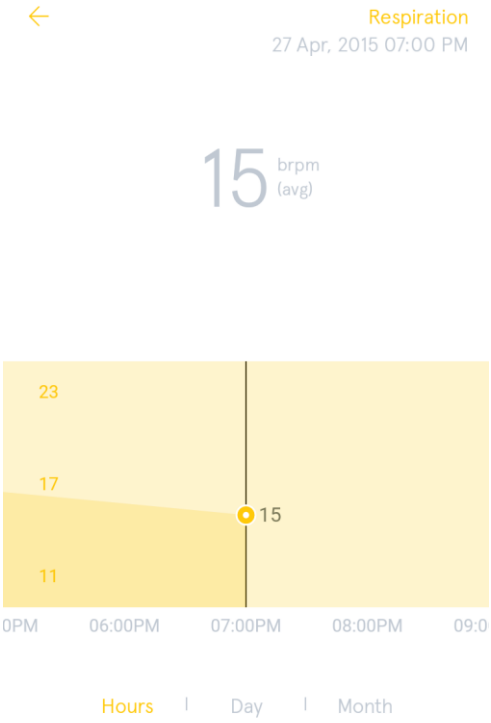
The line graph which is a series of data points connected by lines, illustrates Fitbit™ data. For each Fitbit™ step count data, you can see the corresponding vital statistics taken from Kito overlaid on the graph.

Similarly, you review the graphs for rest of the vitals.

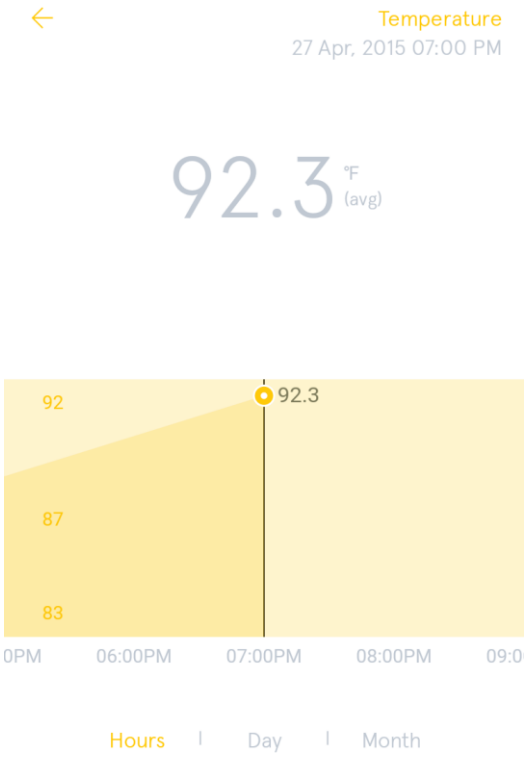
5.3.2 SpO2



5.3.3 Respiration

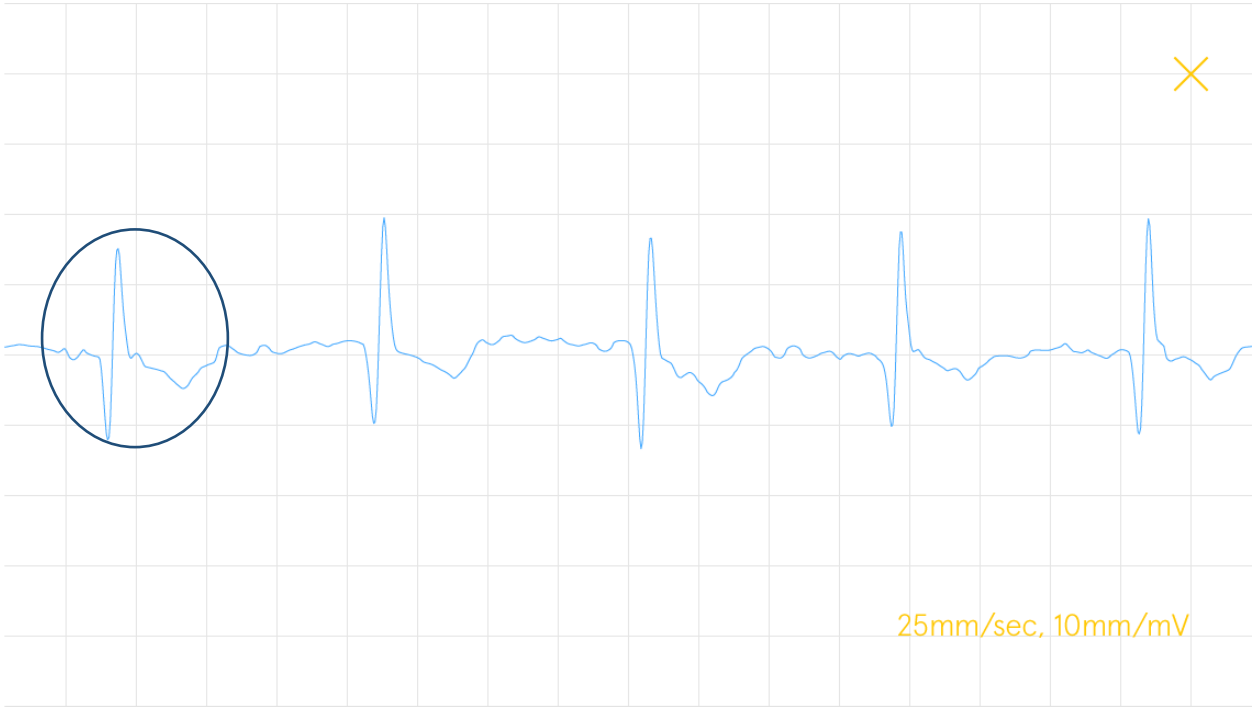


5.3.4 Skin Temperature



5.3.5 ECG

ECG represents the electrical activity of the heart as measured by Kito's electrodes.



This is what you will typically see in an ECG display. The X-axis (horizontal) corresponds to the time in seconds, and Y-axis (vertical) corresponds to the amplitude or voltage in millivolts (mV). The graph highlights a repeating pattern of a tiny wave, followed by a sharp dip, a tall and a sharp spike, followed by a moderate sized wave. This wave pattern represents a single cardiac cycle.

To enhance the ECG graph, you can apply filter to remove noises from the ECG signal. Go to Settings, tap “ECG Filter” switch to toggle it ON or OFF.

Accurate ECG interpretation is complex and involves interpretation of several other parameters in tandem. Hence, we recommend that you show your ECG results to an expert in the relevant medical field for an in-depth analysis and interpretation of the results.

5.4 Share Reports

You can share any reading(s) via email. The application presents your readings in a pdf file with one reading per file.

5.4.1 Single Address

Go to Dashboard, and select a date from your timeline to review the Reading Cards that you want to send. Tap Share and select your preferred Reading Cards. Tap Next, add the email address and send the report.

5.4.2 Multiple Addresses

To share the reports with multiple recipients, follow the procedure explained above and add multiple email addresses.

5.4.3 Automatically to specified address

You can register the email addresses of the people to whom you want to automatically send your data after each reading through “Share Reports”, located under Settings in the app.

Go to Settings, tap “Share Reports” and swipe “Allow Access” to toggle the automatic access ON/OFF. Register the email addresses by adding them to the list.

6 Important Settings

6.1 Adding Multiple Users

Kito supports multi-user access for up to four users per device. All users will have access only to their own individualized dashboards. Tap on the home screen to add a new user. To access an existing user’s dashboard, tap the username.

6.2 Security and Privacy

Your readings are continuously synced with and stored on a secure cloud storage system if your phone is connected to the internet. To secure your Kito account, you can lock your dashboard to prevent other users from accessing your readings. Go to app Settings, swipe “Security Lock” to toggle the dashboard security lock ON/OFF.

6.3 Configure Alerts

Kito provides a way to set personalized reminders to take readings. You can set reminders for weekly or daily alerts.

6.4 Sync Fitbit™

The Kito application overlays the information received from Fitbit™ on its own reading of vitals to indicate how your daily activity is affecting your vitals. It plots your Fitbit™ step count and Kito's vital statistics on the same graph.

Note: *There is a limited support for this functionality; only iOS 7 and later versions are supported.*

7 Care

7.1 Cleaning

Handle Kito with care. Always ensure that your skin is clean and dry when using the device. It is recommended that you clean the device using an alcohol-based sanitizer (containing 70% alcohol) before using it for the first time and before offering it to someone else for use.

7.2 Storage

Store the device in a clean and dry location. Keep out of the reach of infants and kids.

7.3 Maintenance

The battery and the device can maintain their stated performance for up to 2 years. Do not try to repair the device by yourself. Refer to the troubleshooting section to fix the problems you may encounter during usage. You can write to us at *help@azoi.com* in case of further queries.

8 Caution

⚠ Do not wash the device with water or any other chemicals.

⚠ Do not completely drain the device battery.

⚠ Do not expose the device to extreme moisture.

⚠ Do not expose the device in a Magnetic Resonance Imaging ambience.

⚠ Do not expose the device to strong shocks or vibrations.

⚠ Do not cover the sensors or the electrodes in any way.

- ⚠ Do not try to open or repair the device by yourself.
- ⚠ Do not use device with lotion or cream on skin.
- ⚠ Do not charge the device with any other charger apart from the one received with the device.
- ⚠ Do not use the device while it is being charged.
- ⚠ Do not use the device when battery is critically low.
- ⚠ Do not use the device under direct sunlight.
- ⚠ Do not use the device with injured fingers or body parts.
- ⚠ Do not keep the device uncharged for more than six months.
- ⚠ Do not use the device with pacemaker or defibrillator.
- ⚠ Do not use the device if you are suffering from Parkinson
- ⚠ Do not use the device after device lifetime (i.e. 2 years)

Do not store the device in following conditions/locations:

- ⚠ Direct sunlight
- ⚠ High temperature
- ⚠ High humidity
- ⚠ Wet or damp locations where water may get on the unit
- ⚠ Dusty locations
- ⚠ Near fires or open flames
- ⚠ Locations with Strong vibrations
- ⚠ Near strong electromagnetic fields

9 Troubleshooting

9.1 Error Messages

Error Message	Countermeasure	Cause
No Bluetooth	Turn ON Bluetooth.	Communication error between Kito and the application.
No Internet	Connect to the internet.	Kito is not connected to the internet.
Some error occurred at server	Please try connecting again.	The server cannot be reached right now.
Low Battery	Please charge the Kito device.	Kito not sufficiently charged.

9.2 Potential Problems and Solutions

Problem	Solution
No LED indication on Kito after turning ON the Switch	Kito battery is completely drained. Charge Kito until the white indicator light stabilizes.
Unable to pair Kito with the mobile device	Restart your mobile device and re-establish the Bluetooth connection.
Unable to share the readings	Check your internet connection.
Unable to upgrade the firmware	Kito is out of charge. Charge the device until the white indicator light stabilizes. Also confirm if your mobile device is connected to internet. Please note that in case you receive a call while upgrading firmware, the upgrade will not be completed.

Note: *In the event that the above troubleshooting tips do not address your issue, please contact help@azoi.com.*

10 Specifications

ECG Specifications	
ECG channels	1 Lead
Memory	Limited by the phone memory
Recording duration	30 seconds for each reading
Classification of applied parts	Type BF
MDD 93/42/EEC classification	Class II a
Frequency response	0.67 Hz to 40 Hz
CMRR	-105 dB
Input impedance	500 MΩ
Differential range	(+/-)5 mV
ADC sampling rate	250 Hz
ADC resolution	24 bit
Sweep speed	25mm/s
Heart Rate Specifications	
Maximum T-wave amplitude	1.2mV, given 1mV of input QRS amplitude
Averaging	Arithmetic mean over 30 seconds
Response time	a) 4sec for step increase from 80 BPM to 120 BPM b) 8sec for step decrease from 80 BPM to 40 BPM

SpO2 Specifications	
ADC sampling rate	125 Hz
ADC resolution	24 bit
IR wavelength	940 nm
Red wavelength	660 nm
Measuring Methods	
SpO2	Photoplethysmography
Heart rate	ECG driven Heart Rate
Respiration	ECG, PPG driven Respiration
Skin temperature	Contact based temperature sensing
Minimum operating time	30 seconds
Accuracy	
SpO2	+/- 4% rms
Heart rate	+/- 10% or +/- 5 BPM whichever is greater
Respiration	+/-3 BrPM
Skin temperature	+/- 0.3°C

Measuring Range	
SpO2	70% to 100%
Heart rate	30 BPM to 200 BPM
Respiration	5 BrPM to 24 BrPM
Skin temperature	15 °C to 40 °C (59 °F to 104.0 °F)
Power Requirements	
Battery type	Li-ion Polymer
Battery life	2 months *****
Battery capacity	(90X2) mAh
Output voltage	3.7 volts
Charging mode	Rechargeable
Compatibility	iPhone - 5/5s Android (OS version 4.3 or higher)
Wireless communication	Bluetooth 4.0 - Bluetooth Low Energy
Battery charging time from depletion to 90%	6 hours
Charger Specifications	
Input	USB 2.0
Output	DC 5V+/-10%, @500mA, with 1KV DC-DC IEC60950 certified isolation

Environmental Specifications	
Operational temperature	+10 °C to +40 °C (50 °F to 104 °F)
Operational relative humidity	45% to 70% (non-condensing)
Storage temperature	0 °C to +35 °C (32 °F to 95 °F)
Storage relative humidity	45% to 70% (non-condensing)
Physical Characteristics	
Dimensions	128.03mm x 62.77mm x 12mm
Weight	33.76 gms
Colours	Pantone Black
Ingress protection	IP22 2- Protected against solid foreign objects of 12.5 mm and greater 2-Protection against vertically falling water drops when ENCLOSURE tilted up to 15°

* Battery life varies by usage and settings.

Symbols	**Description**
	Refer to instruction manual/booklet
	Keep away from rain

EC REP	European Union Representative details
CE 0086	CE Mark as per Notified Body BSI
	Caution, consult accompanying documents
	Temperature Limitation
	Type BF
	Symbol for compliance with Federal Communication Commission
	Waste Electrical and Electronic Equipment
	Refers the Manufacturer
SN	Serial number
	Date of Manufacture
IP22	Ingress Protection

11 Deactivate

11.1 Unpair

You can remove the existing Kito pairing.

Note: *The pairing can be undone even if Kito is not in the vicinity. If you've lost Kito, you can unpair it and add a new Kito.*

Tap "Forget this Kito" and wait till the pairing is undone. To pair again, tap "Pair this Kito" and follow the on-screen pairing instructions.

11.2 Uninstall

Go to **Settings**, tap **Profile** and tap **Deactivate Account**.

Deactivating account permanently deletes your profile and vital readings from the application.

11.3 Disposal

The device should not be discarded with household waste.

To prevent possible harm to human health and environment, dispose it off as a recyclable waste to promote sustainable reuse of material resources.

Please carry out disposal for battery in accordance with the national and other local regulations.

12 International Standards and Compliances

12.1 Compliance to Standards

Standard#	**Revision**	**Description**
EN ISO 13485	2012	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971	2012	Medical devices - Application of risk management to medical devices
ISO 80601-2-61	2011	Medical electrical equipment — Part 2-61: Particular requirements for basic safety and essential performance of pulseoximeter equipment
EN 62304	2008	Medical device software -- Software life cycle processes
IEC 62366	2008	Medical devices - Application of usability engineering to medical devices
IEC 60601-1	2012	Medical electrical equipment - Part 1: General requirements for basic safety & essential performance
IEC 60601-2-27	2011	Medical electrical equipment – Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment
EN ISO 10993-1	2009	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
IEC-60601-1-11	2010	Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

IEC-60601-1-2	2010	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance- Collateral Standard: Electromagnetic disturbances- Requirements and tests
IEC-61000-4-2	2008	Part 4-2: Testing and measurement techniques- Electrostatic discharge immunity test
IEC-61000-4-3	2006	Part 4-3: Testing and measurement techniques- Radiated, radio-frequency, electromagnetic field immunity test
IEC-61000-4-8	2009	Part 4-8: Testing and measurement techniques- Power frequency magnetic field immunity test
CISPR 11	2010	Electromagnetic Radiation Disturbance (Radiated Emissions) CISPR 11 (Class A/B, Group ½)
R&TTE	1999	Radio equipment and all equipment intended to be connected to public telecommunications networks
ROHS	Directive 2011/65/EU	Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment . Consolidated version of 30 April 2015.

12.2 Electromagnetic Emissions

Guidance and manufacturer's declaration – electromagnetic emissions		
Kito is intended for use in the electromagnetic environment specified below. The user should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1 Class B	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	N/A	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	N/A	

Voltage fluctuations/flicker emissions IEC 61000-3-3	N/A	

12.3 Electromagnetic Immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
Kito is intended for use in the electromagnetic environment specified below. The user should ensure that it is used in such an environment.			
Immunity test	**IEC 60601-1-2 test level**	**Compliance level**	**Electromagnetic environment –guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 6 kV contact +/- 8 kV air	+/- 6 kV contact +/- 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	NA	NA	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	NA	NA	Mains power quality should be that of a typical commercial or hospital environment.
Interruptions and voltage variations on power supply input lines IEC 61000-4-11	NA	NA	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a

			battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

*Mains power electromagnetic compatibility applies to the charger, which meets applicable IEC 61000 requirements.

12.4 Guidelines and Manufacturer's Declaration – Electromagnetic Immunity

Guidelines and manufacturer's declaration – electromagnetic immunity			
Kito is intended for use in the electromagnetic environment specified below. The user should ensure that it is used in such an electromagnetic environment.			
IMMUNITY test	**IEC 60601-1-2 TEST LEVEL**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	NA	NA	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated

Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GH	3 V/m	from the equation applicable to the frequency of the transmitter. Recommended separation distance d = 1,2√P d = 1,2√P 80 MHz to 800 MHz d = 2,3 √P 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:

Note 1: *At 80 MHz and 800 MHz, the higher frequency range applies.*

Note 2: *These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.*

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

13 FCC Statement

The changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may

cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

FCC Caution

This device complies with Part15 of the FCC Rules. Operation is subject to the following two conditions:

1. This device may not cause harmful interference and
2. This device must accept any interference received, including interference that may cause undesired operation.

RF Exposure Warning

The equipment complies with RF exposure limits set forth for an uncontrolled environment. The antenna(s) used for this transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

14 Recommended separation distance

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and Kito			
Kito is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of Kito can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Kito.			
Rated Maximum output power of transmitter, P[W]	**Separation distance according to frequency of transmitters, d [m]**		
	150KHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3

10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: *At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.*

Note 2: *These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.*

15 Declaration and Disclaimers

- The user is an intended operator.
- Kito may be interfered with by other equipment, even if that other equipment complies with the CISPR EMISSION requirements.
- Portable and mobile RF communications equipment can affect Kito.

Immunity Test	**IEC 60601-1-2 test level**	**Compliance level**	**Electromagnetic environment-guidance**
Radiated RF IEC 61000-4-3	3 V/m80 MHz to 2.5 GHz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the EQUIPMENT or SYSTEM including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Interference may occur in the vicinity of equipment marked with the following symbol.
Electrostatic discharge (ESD)IEC 61000-4-2	+/-6kV contact 8kV air	6kV contact 8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.

16 Acronyms

ECG (EKG)	Electrocardiograph
SpO2	Blood Oxygen Saturation level
PPG	Photoplethysmography